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510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1600 Millrace Drive, Suite 307, Eugene, OR 97403
541-687-7962

Contact name: Linda J. Bovard, Bovard Consulting LLC
29611 Simmons Road, Eugene, OR 97405
541-345-5431

Date summary prepared: November 19, 2004

Device name:

Proprietary name: Geodesic Photogrammetry System (GPS)
Common or usual name: EEG accessory
Classification name: Electroencephalograph, 84 GWQ
Class II, 21 CFR 882.1400.

Legally marketed device for substantial equivalence comparison:

There is no predicate accessory for EEG. The Geodesic Photogrammetry System (GPS) is substantially equivalent to surgical cameras used as recording accessories to surgical procedures (21 CFR 878.4160, 79 KQM). In the same way, this accessory does not alter the intended use, the environment for use, or the target population of the previously cleared Electrical Geodesics, Inc. Geodesic EEG System (EGI GES) products with which it can be used. It simply records the use of the main product.

Description of the device:

The GPS consists of a geodesic dome structure containing 11 mounted cameras, a steel supporting structure, a dedicated computer, and accompanying software. It is used with a Geodesic Sensor Net and any EGI Geodesic EEG system. It allows the user to record the locations of the dense array EEG electrodes on a patient's head. No part of the Geodesic Photogrammetry System touches the patient.

Intended use of device:

The Geodesic Photogrammetry System is intended for use in recording precise locations of EEG electrodes in the Geodesic Sensor Net on a patient's head.

Technological characteristics:

The Geodesic Photogrammetry System is an accessory to EGI's GES products. It contains digital cameras arranged to record EEG electrode placement. The cameras are controlled by software. The GPS does not change the main GES products in any way.

Testing conducted:

Testing was conducted to international standards related to electrical safety and electromagnetic compatibility. The GPS passed all essential performance tests.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electrical Geodesics Incorporated
c/o Ms. Linda J. Bovard, RAC
Bovard Consulting LLC
29611 Simmons Road
Eugene, Oregon 97405

Re: K043309
Trade/Device Name: Geodesic Photogrammetry System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, KQM
Dated (Date on orig SE ltr): November 22, 2004
Received (Date on orig SE ltr): December 1, 2004

APR - 9 2012

Dear Ms. Bovard:

This letter corrects our substantially equivalent letter of January 26, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 1

Indications for Use

510(k) Number (if known): K043309

Device Name: Geodesic Photogrammetry System

Indications for Use: The Geodesic Photogrammetry System is intended for use in recording precise locations of EEG electrodes in the Geodesic Sensor Net on a patient's head.

Prescription Use _X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043309